K092568

# 4. 510(k) Summary according to 807.92(c)

**Contact:** Tim Lusby
Amendia™, INC
1155 Allgood Road, Suite 6
Marietta, GA 30062
770-874-0935

NOV 17 2009

**Trade Name:** Spartan $S^3$ Facet System
**Product Class:** Unclassified
**Classification:** Unclassified
**Product Codes:** MRW
**Panel Code:** 87

**Indications for Use:** The Spartan $S^3$ Facet System is indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels:

1) Trauma, including spinal fractures and/or dislocations;
2) Spondylolisthesis;
3) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity;
4) Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

The Spartan $S^3$ Facet System will provide temporary stabilization as an adjunct to spinal fusion.

**Device Description:** The Spartan $S^3$ Facet System is a permanent implant device made from a titanium alloy TI 6AL4V-ELI. It is to be implanted from the posterior approach. The device is provided in two diameters and each diameter screw is provided in multiple lengths to accommodate the various anatomy of the spine. The device is intended to provide mechanical support and stability to the implanted level until biologic fusion is achieved.

**Predicate Device(s):** The predicate devices previously cleared by FDA are the DISCOVERY Facet Screw (K012773), Triad Facet Screw System (K020411), Oasys Bone Screw (K031657) and the Trans1 Facet Screw (K073515).

**Performance Testing:** The pre-clinical testing performed indicates that the Spartan $S^3$ Facet System is substantially equivalent to the predicate devices and is adequate for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Amendia, Inc.
% Silver Pine Consulting
Mr. Richard Jansen
President
13540 Guild Avenue
Apple Valley, Minnesota 55124

NOV 17 2009

Re: K092568
Trade/Device Name: Spartan $S^3$ Facet System
Regulation Number: Unclassified
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: MRW
Dated: August 19, 2009
Received: August 20, 2009

Dear Mr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 3. Statement of Indications for Use

510(k) Number (if known): K092568

The Spartan $S^3$ Facet System is indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels:

1) Trauma, including spinal fractures and/or dislocations;
2) Spondylolisthesis;
3) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity;
4) Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

The Spartan $S^3$ Facet System will provide temporary stabilization as an adjunct to spinal fusion.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092568

Concurrence of CDRH, Office of Device Evaluation (ODE)

page 1 of 1